K011145

JUN 2 5 2001

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Jennifer Tribbett

Date Prepared: March 16, 2001

2) Device name

Proprietary name: Roche Diagnostics Reflotron Amylase

Common name: α-amylase

Classification name: Amylase test system
75JFJ
Device Class II

3) Predicate device

We claim substantial equivalence to the currently marketed Roche Diagnostics Reflotron Amylase (K874704)

4) Device Description

The Roche Diagnostics Reflotron Amylase test is intended for use for the quantitative determination of α-amylase in whole blood, serum and plasma with the Reflotron System in the professional health care setting.

The test reaction is based upon the α-amylase-specific chromogenic substrate. Indolyl-α, D-maltoheptaoside is cleaved by amylase. This is followed by a glucosidase reaction which yields free indoxyl. Indoxyl, then, is coupled with a diazonium salt to form a red-violet dye. This dye formation is measured at timed intervals to determine the kinetic activity of α-amylase.

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5) Intended use

The Roche Diagnostics Reflotron Amylase test is intended for use for the quantitative determination of α-amylase in whole blood, serum and plasma with the Reflotron System in the professional health care setting.

6) Substantial equivalence – Similarities and Differences

Similarities:

The intended use, test principle and reagent composition are identical to the Reflotron Amylase cleared under K874704.

Differences:

This submission is being provided for the change in the reference method used to calibrate the Amylase reagent.

Reflotron Amylase was previously calibrated against an α-amylase PNP reference method. The calibration method has now been changed to an α-amylase liquid reference method.

The α-amylase liquid reference is a kinetic method based on the cleavage of 4,6-ethylidene-(G_7)-1,4-nitrophenyl-(G_1)-α,D-maltoheptaoside (Ethylidene Protected Substrate=EPS) by α-amylase and subsequent hydrolysis of all the degradation products to p-nitrophenol with the aid of α-glucosidase (100% chromophore liberation).

This liquid reference method has lower reference values; therefore, the Reflotron Amylase reagent will also have a lowered measuring range. This submission provides the validation data collected to support the reduced measuring range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 5 2001

Ms. Jennifer Tribbett
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: 510(k) Number: K011145
Trade/Device Name: Roche Diagnostics Reflotron Amylase
Regulation Number: 862.1070
Regulatory Class: II
Product Code: JFJ
Dated: June 7, 2001
Received: June 8, 2001

Dear Ms. Tribbett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011145
Device Name: Roche Diagnostics Reflotron Amylase

Indications for Use:

The Roche Diagnostics Reflotron Amylase test is intended for use for the quantitative determination of α-amylase in whole blood, serum and plasma with the Reflotron System in the professional health care setting.

Elevated α-amylase can be indicative of acute or chronic pancreatitis, although it may be the result of an extrapancreatic condition. Increases in serum amylase are found in parotitis, renal failure or macroamylasia.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011145

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)